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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,080	04/26/2001	Philippe J. Goix	A-69516/AJT	9621
7590	01/28/2004		EXAMINER	
Aldo J. Test FLEHR HOHBACH TEST ALBRITTON & HERBERT LLP Four Embarcadero Center, Suite 3400 San Francisco, CA 94111-4187			GABEL, GAILENE	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 01/28/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant No.	Applicant(s)	
	09/844,080	GOIX ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 3-38 is/are pending in the application.
- 4a) Of the above claim(s) 12-33 and 38 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-11 and 34-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1 and 3-38 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u> .	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/9/03 has been entered.

Amendment Entry

2. Applicant's amendment and response filed 11/12/03 in Paper No. 16 is acknowledged and has been entered. Claims 1, 3, and 4 have been amended. Claim 2 has been cancelled. Claim 38 has been added. Claims 12-33 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1 and 3-38 are pending.

Newly submitted claim 38 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: elected Group 1, claims 1, 3-11, and 34-37, are drawn to a particle analyzing apparatus which have independent and distinct structural features from non-elected Group IV, claims 26-28, which are drawn to a method of detecting tagged particles using the particle analyzing apparatus. Thus, newly submitted claim 38 which is drawn to a method of analyzing

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particles would have been restricted out with Group IV if originally presented with the application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-33 and 38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, claims 1 and 3-38 are pending. Claims 1, 3-11, and 34-37 are under examination.

Rejections Withdrawn

3. The rejections of claim 2 are now moot in light of Applicant's cancellation of the claim.

4. In light of Applicant's amendment, the rejection of claims 1-3, 5, 8, and 34 under 35 U.S.C. 102(b) as being clearly anticipated by Goix (WO 98/57152), is hereby, withdrawn.

5. In light of Applicant's amendment, the rejections of claims 4, 6, 7, 9-11, and 35-37 under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of in view of Mochida et al. (US 5,147,607), in view of Hirako (US 5,135,302), in view of von Behrens et al. (US 5,378,633), and in view of Bernstein et al. (US 5,478,750), respectively, are hereby, withdrawn.

Claim Objections

6. Claims 5-7, 10, and 11 are objected to for depending from a cancelled claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3-11 and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reason of record.

Claim 1, in lines 6, 7, and 8, is indefinite in lacking clear antecedent support in reciting, "capillary channel". It is further unclear what structural and functional cooperative relationship exists between the former recitation of "capillary" and the latter recitation of "capillary channel" in claim 1.

Claim 35, preamble, is non-idiomatic and, therefore, confusing in reciting, "including".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3, 5, 8, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US Patent 3,827,304).

Goix discloses an apparatus for detecting particles (microparticles) such as bacteria, virus, fungus, and parasitic cysts, i.e. Giardia, or microscopic beads, in fluid samples (see page 5, lines 12-29 and Figures 2, 3, and 4). The apparatus comprises an elongate cylindrical capillary channel with a predetermined internal cross-sectional area configured to admit particles one at a time, i.e. singulate, as a sample volume passes through analysis area, a pump for drawing sample containing the particles through the channel and flowing the particles along the capillary channel into its other end. The pump may be a syringe or a peristaltic pump (see page 6, lines 10-26). The apparatus further includes a light source (laser) which generates a laser beam for illumination and focus through one or more lenses onto a test volume of the sample

being analyzed (see page 7, lines 5-9). The apparatus also includes a detector, i.e. photomultiplier tube, for detecting particles that flow along the capillary tube, the detector having a collecting lens for intercepting (gathering) fluorescent light emitted by particles, and a slit (interference filter(s)) in front of the photomultiplier tube to block unwanted light, i.e. filter out resonant light (see page 7, lines 5-20). The apparatus may optionally have a dichroic beam splitter (diffraction grating) upon which fluorescence emissions are gathered and reflected or passed through for receiving and imaging of transmitted or reflected light onto multiple detector array which provides an output signal (see page 7, line 21 to page 8, line 12). A set of interference filters are used to single out fluorescence emission of fluorescent substance used to tag the particles.

Goix differs from the instant invention in failing to disclose that the second end of the capillary is suspended for immersion into a sample so that the pump draws the sample into the second end of the capillary channel.

D'Autry discloses an apparatus for drawing repetitive liquid samples for analysis. The apparatus has a capillary tube having an end, i.e. second end, (first conduit) upon which the sample is introduced by immersion of the pipette into the sample and a first end (second conduit) connected to a pump which serves to draw sample into the second end of the capillary channel (see Derwent Abstract or column 2 and Figure 1 of US Patent 3,827,304).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate a capillary and pump such as in the analytical apparatus taught by D'Autry into the apparatus as taught by Goix because D'Autry specifically

taught that such configuration provides many different advantages including accuracy from elimination of carry-over contamination, reduction in the volume of sample required, reduction in time required for analysis, and adaptability with automation. Accordingly, one of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the capillary and pump as taught by D'Autry into the apparatus of Goix.

9. Claims 6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US Patent 3,827,304) as applied to claims 1-3, 5, 8, and 34 above, and further in view of Hirako (US 5,135,302).

Goix and D'Autry have been discussed supra. Goix and D'Autry differ from the instant invention in failing to disclose an off-axis detector which detects light scattered by particles in the test volume. Goix and D'Autry further differ in failing to disclose a detector which includes a beam blocker for blocking direct light so that detector only receives scattered light.

Hirako discloses an apparatus which includes a capillary channel (flow cell) containing a flow stream of particles which flows one at a time, i.e. singulated, based on hydrodynamic method (see Abstract). The apparatus specifically includes a forward scattered light detector for detecting light scattered by particles in the same direction of light source and an off-axis particle detector, i.e. a right angle scattered light detector for detecting light scattered or radiated in a right angle with respect to the direction of the

radiating light (see Figure 2). The apparatus also includes light collecting lenses for intercepting fluorescent light and slits (pinholes) for blocking unwanted light from detectors. Hirako also discloses that the forward scattered light detector includes a beam blocker for blocking direct light so that the detector only receives scattered light.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate an off-axis detector as taught by Hirako into the particle analyzing apparatus as taught by Goix as modified by D'Autry because off-axis detectors such as right angle scattered light detectors as taught by Hirako allow for detection of other parameters in a particle or cell such as granularity, which are not otherwise detected using forward axial scattered light detector. One of ordinary skill in the art at the time of the instant invention would have been motivated to further complement the particle analyzing apparatus of Goix and D'Autry with the beam blocker as taught by Hirako because beam blockers assist in blocking direct light; thus, allowing light scatter detectors to receive only desired scattered light.

10. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US Patent 3,827,304) as applied to claims 1-3, 5, 8, and 34 above, and further in view of Bernstein et al. (US 5,478,750).

Goix and D'Autry have been discussed *supra*. Goix and D'Autry differ from the instant invention in failing to disclose a detection system wherein a beam splitter receives gathered light and reflects light above a predetermined wavelength and passes

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light below the predetermined wavelength. Goix and D'Autry further differ from the instant invention in failing to disclose that the predetermined wavelength is 620 nm, the light below the predetermined wavelength is 580 nm, the light above the predetermined wavelength is 675 nm, and that a filter is interposed between the beam splitter and each detector of the detection system.

Bernstein et al. disclose a compact optical system in an analyzer which allows for simultaneous measurement of light absorption at a plurality of wavelengths. Specifically, Bernstein et al. disclose a series of detector assemblies; each detector assembly comprising a beam splitter, an interference filter, and a photodetector. The beam splitter functions to receive gathered light, reflect light above a predetermined wavelength, and transmit (pass) light below a predetermined wavelength (see column 4, lines 39-66).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Bernstein of multiple detection assembly which can be programmed to reflect or transmit at predetermined wavelengths with the apparatus as taught by Goix as modified by D'Autry because Bernstein specifically taught application of the compact optical system to any particle analyzing apparatus such as those taught by Goix and D'Autry.

Additionally, it is maintained that wavelength ranges, i.e. 620 nm, below 580 nm, and above 675 nm, are all result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover

an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 36-37 are for any particular purpose or solve any stated problem, and the prior art teaches that wavelength ranges may vary according to the sample being analyzed and the purpose it is used, parameters appear to work equally as well. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US Patent 3,827,304) as applied to claims 1-3, 5, 8, and 34 above, and further in view of Mochida et al. (US 5,147,607).

Goix and D'Autry have been discussed supra. Goix and D'Autry differ from the instant invention in failing to disclose that the capillary channel is rectangular.

Mochida et al. disclose an apparatus having a fluid flow channel. Mochida et al. disclose that the fluid flow channel may have a variation of cross-sectional shapes such as rectangular, concave, triangular, etc. (see column 7, lines 66-68 and column 8, lines 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the cylindrical cross-sectional shape of the capillary flow channel as taught by Goix as modified by D'Autry with rectangular cross-sectional shape as taught by Mochida because a rectangular cross-sectional shape of a capillary channel constitutes an obvious variation of cross-sectional shapes in fluid flow channel devices.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US Patent 3,827,304) as applied to claims 1-3, 5, 8, and 34 above, and further in view of von Behrens et al. (US 5,378,633).

Goix and D' Autry have been discussed supra. Goix and D'Autry differ from the instant invention in failing to disclose using a detector that detects a change in impedance caused by the flowing particles.

Von Behrens et al. disclose optical flow cytometric devices for fluorescence tagging and light scatter measurements of particles such as cell populations. Specifically, von Behrens et al. disclose the device having an impedance channel for detecting and enumerating leucocyte nuclei from intact cells (see column 29, lines 27-

35). The impedance channel detects a change in electrical impedance across an orifice caused by the flow of particles in the sample (see claim 5).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the detector of von Behrens that detects a change in impedance with the particle analyzing apparatus of Goix as modified by D'Autry because von Behrens specifically taught application of the impedance channel for measuring electrical impedance of particles such as cells using any optical flow analyzing device such as those taught by Goix and D'Autry.

Response to Arguments

13. Applicant's arguments with respect to claims 1, 3-11, and 35-37 have been considered but are moot in view of the new grounds of rejection.

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Christopher L. Chin

Gailene R. Gabel

Patent Examiner

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January 21, 2004

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CHRISTOPHER L. CHIN

PRIMARY EXAMINER

GROUP 1800/641